



## Alere Receives CE Mark for Alere™ HIV Combo

*Rapid 4<sup>th</sup> Generation HIV Test Detects HIV 1/2 antibodies and HIV-1 p24 in 20 minutes*

**WALTHAM, Mass.**, Feb. 17, 2015 – Alere Inc., a global leader in rapid diagnostic tests, today announced it has received CE Marking in Europe for Alere HIV Combo, a rapid point-of-care test that detects both HIV-1/2 antibodies and the HIV-1 p24 antigen, which can appear days after infection and prior to HIV-1/2 antibodies. Alere HIV Combo detects all known subtypes and recombinants of the virus more prevalent in Africa, Europe, Asia and Latin America.

Using serum, plasma, fingerstick or venous whole blood specimens, Alere HIV Combo can deliver fast, accurate results in 20 minutes. The test will initially be launched in the UK, France, Switzerland and Spain. Alere is also applying for WHO prequalification to expand availability of the 4<sup>th</sup> generation HIV point of care tests to Africa. Further global registrations are underway in Asia and will begin in Latin America.

“As the market leader in HIV rapid diagnostics at the point of care, Alere continues to drive innovation and bring to market the best possible technologies to help detect HIV sooner,” said Avi Pelossof, Alere Global President of Infectious Disease. “The failure to diagnose acute infections at the point of care represents an important public health problem. The new Alere HIV Combo test will increase opportunities for case finding, particularly in high-risk communities that would not be detected using 2<sup>nd</sup> and 3<sup>rd</sup> generation antibody-only tests.”

Alere HIV Combo detects acute infection, which is defined as the interval between the appearance of HIV RNA in plasma and the detection of HIV-1 specific antibodies. Persons with acute infection may be up to 10 times more likely to transmit HIV than individuals with established infection.<sup>1</sup> With use of Alere HIV Combo, HIV can be detected earlier, facilitating fast and appropriate linkage to care.

Including the new addition of Alere HIV Combo, Alere offers diagnostic solutions for the complete continuum of HIV care from initial screening and diagnosis to staging and ongoing monitoring. For more information, visit [www.alerehiv.com](http://www.alerehiv.com).

Note: The Alere HIV Combo is not approved for sale in the U.S. Alere Determine™ HIV-1/2 Ag/Ab Combo is CLIA-waived and available in the U.S.

## **About Alere**

Because **Knowing now matters™**, Alere delivers reliable and actionable information through rapid diagnostic tests, resulting in better clinical and economic healthcare outcomes globally. Headquartered in Waltham, Mass., Alere focuses on rapid diagnostics for infectious disease, cardiometabolic disease and toxicology. For more information on Alere, please visit [www.alere.com](http://www.alere.com).

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<sup>i</sup> Wawer MJ, Gray RH., Sewankambo NK et al. Rates of HIV-1 transmission per coital act by-stage of HIV-1 infection in Rakai, Uganda. *Journal of Infectious Disease* 2005;191: 1403-9.